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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,875	04/11/2005	Hans-Georg Kreysch	MERCK-2989	2265

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EXAMINER

GODDARD, LAURA B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/530,875

Applicant(s)

KREYSCH, HANS-GEORG

Examiner

Laura B. Goddard, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

A. The species are as follows:

(a) a bispecific antibody wherein said second ErbB receptor molecule type is ErbB1 (EGFR), and wherein the bispecific antibody binds to different epitopes located on the same ErbB receptor molecule type (claims 2, 8, 10, 14, 15), or

(b) a bispecific antibody wherein said second ErbB receptor molecule type is ErbB2 (HER2), (claims 3, 9, 11, 16, 17), or

(c) a bispecific antibody wherein the antibody binds to different epitopes located on different ErbB receptor molecule types wherein the second receptor molecule type is not ErbB2 or ErbB1 (9, 11, 16).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the bispecific antibodies comprise distinct antigen binding sites that bind to different molecule, hence are structurally and functionally distinct species of antibodies. The following claim(s) are generic: claim 1.

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Applicant is further required to elect a species from B below:

B. The species are as follows:

(a) a bispecific antibody wherein the first antigen-binding site derives from Mab425 (claims 12), or

(b) a bispecific antibody wherein the first antigen-binding site derives from Mab225 (claim 13).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the bispecific antibodies comprise distinct antigen binding sites that bind to different epitopes, hence are structurally and functionally distinct species of antibodies. The following claim(s) are generic: claim 1.

Applicant is further required to elect a species from C below:

C. The species are as follows:

(a) a pharmaceutical composition further comprising a monospecific anti-ErbB antibody and kit (claim 22, 23, 28, 29), or

(b) a pharmaceutical composition further comprising a cytotoxic agent and kit (claim 24-27, 30 and 31).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: pharmaceutical

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compositions further comprise structurally and functionally distinct molecules. The following claim(s) are generic: claim 1.

If Applicant elects (a) in C above as drawn to a monospecific anti-ErbB antibody, Applicant is further required to elect a species from D below:

D. The species are as follows: **Mab 425, Mab 225, or Mab 4D5** (claims 23 and 29).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the monoclonal antibodies distinct antigen binding sites that bind to different epitopes or to different molecules, hence are structurally and functionally distinct species of antibodies. The following claim(s) are generic: claim 1.

If Applicant elects (b) in C above as drawn to a cytotoxic agent, Applicant is further required to elect a species from E below:

E. The species are as follows:

- (a) a chemotherapeutic agent (claims 25 and 26, 31),**
- (b) ErbB receptor inhibitor (claim 27, 31),**
- (c) VEGF receptor inhibitor (claim 27, 31),**
- (d) tyrosine kinase inhibitor (claim 27, 31),**
- (e) protein kinase A inhibitor (claim 27, 31),**
- (f) anti-angiogenic agent (claim 27, 31),**

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(g) anti-hormonal agent (claim 27, 31), or

(h) cytokine (claim 27).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each molecule is a structurally and functionally different molecule. The following claim(s) are generic: claim 1.

CLAIMS WILL BE EXAMINED AS DRAWN TO THE ELECTED SPECIES.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
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JEFFREY SIEW
SUPERVISORY PATENT EXAMINER